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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,394	09/05/2003	Shaohong Qu	035718/268948	8698

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EXAMINER

IBRAHIM, MEDINA AHMED

ART UNIT PAPER NUMBER

1638

DATE MAILED: 10/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/656,394

Applicant(s)

QU ET AL.

Examiner

Medina A. Ibrahim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: SL error report

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### **DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's response filed 07/20/05 in reply to the Office action of 03/11/05 has been entered. Claims 1-2, 6, and 10-12 are amended. Therefore, claims 1-21 are pending and are examined.

The CRF filed 09/05/05 has not been entered because the CRF does not comply the requirements for sequence submissions in computer readable form as set forth in 37 CFR 1.824. See attached Raw Sequence Listing Error Report. Applicant is required to provide substitute Sequence Listings that comply with 37 CFR 1.824. See MPEP 2425.

All previous objections and rejections not set forth below have been withdrawn.

#### ***Claim Rejections - 35 USC § 112***

Claims 1-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the construct designated as C2 comprising NB2, NBS3 and partial sequences of NBS1 and NBS4, and a method of inducing blast disease resistance in a transgenic plant using said C2 construct, does not reasonably provide enablement for an isolated nucleic acid molecule having at least 95% sequence identity to SEQ ID NO: 7 or a nucleic acid molecule that hybridizes to a complement of SEQ ID NO: 7, and encoding a polypeptide that confers resistance to blast, a nucleic acid molecule that encodes a fragment of at least 40 contiguous amino acids of SEQ ID NO: 8 and having blast resistance activity, and methods of transforming plants with said nucleic acid molecules to create or enhance disease resistance in a transgenic

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plant. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with these claims. This rejection is repeated for the reasons of record as set forth in the last Office action of 03/11/05. Applicant's arguments filed 07/20/05 have been fully considered but are not deemed persuasive.

Applicant correctly states the in re Wands factors for determining whether undue experimentation is required to make and/or use the claimed invention. Applicant argues that instant specification provides the Pi2-like sequence of SEQ ID NO: 7, provides guidance for determining regions that would tolerate modifications, hybridization conditions fragments, percent of sequence identity, and provide sequence alignment showing conserved regions between known resistance gene, Pib2 with the candidate Pib gene of the instant invention. Applicant points to pages 5-6, 12, pages 19-22, and of Figure 5. Applicant cites Ex Parte Sun, 2003-1993 (Bd. Pat. App. Int., Jan. 20, 2004) and Ex parte Vogelstein, 2002-0779 (Bd. Pat. App. Int., Dec. 30, 2002) to support this position (response, pp. 10-12).

These are not persuasive because the invention as claimed is not supported by enabling disclosure taking into account the in re Wands factors as set forth in the last Office action. Applicant provides SEQ ID NO: 7 encoding a polypeptide with LRR and NBS domains as a blast resistance candidate nucleic acid. However, the only working example disclosed does not support any disease resistance activity by SEQ ID NO: 7. Neither the prior art nor Applicant's response provide evidence that all candidate resistance genes are functional nor that it would enhance or create resistance upon

expression in a transgenic plant.

Parker et al (The Plant Cell (1996), vol. 8, pp. 2033-2046) teach that despite the insights that resistance genes have LRR and/or NBS, the function of these genes cannot be predicted from sequence structure alone and functional tests are required to determine their role in resistance (see the whole document, especially page 2042, column 1, last full paragraph).

Bennetzen, J (US 2002/0108140, publication date 08/08/02) who teaches LRR-NBS resistant gene family. At page 14, 2<sup>nd</sup> column, the last full paragraph, Bennetzen states "...homology based isolation of R genes could be beneficial to cloning or positioning real R genes conferring resistance to bacterial, fungal, viral, and nematode pathogens. However, whether or not these RGH (Resistance Gene Homolog) are functional R genes conferring resistance to any known or unknown pathogens of maize, sorghum or rice is not known. Even for RGHs mapped near to known R genes, cDNA analysis and detailed cosegregation tests are still needed, and further DNA complementation transformation testing is also necessary to confirm their role in disease resistance".

Also, Applicant's own specification teaches that blast resistance phenotype in the transgenic rice is the function of Pi gene cluster and not by individual gene expression in the plant. Example 14 of the specification teaches transformation of susceptible rice plants with a construct containing NBS2 (SEQ ID NO: 3), NBS3 (SEQ ID NO: 5) and partial sequence of NBS1 and NBS4 (SEQ ID NO: 7). Therefore, it is clear from Applicant's own working example that expression of all genes in the cluster is required

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for the blast resistance phenotype in the transgenic rice plants. Applicant has provided no convincing evidence to support the conclusion that SEQ ID NO: 7 is responsible for the blast resistance phenotype exhibited by the transformed rice plants.

Regarding parts (c) , (d), and (e) of claims 1, 6 and 12, since SEQ ID NO: 7 has no blast resistance activity as shown by the only working example in the specification, sequences having less than 100% identity thereto, including sequences with 95% identity to SEQ ID NO: 7; sequences that hybridize to a complement thereof; and sequences encoding polypeptides having 40 contiguous amino acids of SEQ ID NO: 8, are not expected to provide blast resistance activity in a transgenic plant.

Applicant further argues that the quantity of experimentation required for producing functional Pi2-like variants and use them for the production of transgenic plants with blast resistance would not be undue. Applicant asserts that the in re Wands factors favor this position.

This is not found persuasive because if the amount of experimentation required to practice the invention as claimed is routine why not Applicant disclose a single nucleic acid that is functional and having blast resistance activity in a transgenic plant. Examiner agrees with Applicant that identification of a sequence with LRR-NBS domain, determination of sequences with 95% identity to SEQ ID NO: 7 and sequences that hybridize to a complement of SEQ ID NO:7 or sequences encoding a fragment of 40 contiguous amino acids of SEQ ID NO: 8 are known processes. However, whether one can achieve said sequences with blast resistance phenotype in a transgenic plant is not predictable.

Applicant further argues that claims in the instant specification are similar in scope to those at issue in the Ex Parte Sun, 2003-1993 (Bd.Pat.App. Int., Jan. 20, 2004) and Ex parte Vogelstein, 2002-0779 (Bd. Pat. App. Int., Dec. 30, 2002). However, Examiner finds no relationship between instantly claimed invention, drawn to nucleic acid sequences encoding LRR-NBS polypeptide and claims drawn to tyrosine kinase polynucleotide in Ex Parte Sun or the human p53 tumor suppressor gene in Ex parte Vogelstein, except that they all involve nucleic acid variants. While the decisions in both Ex Parte Sun and Ex parte Vogelstein are not binding precedent of the board, and do not apply to all patent applications claiming nucleic acid variants, Examiner notes that these two patents are not analogous to the instant application. For example, in Ex Parte Sun, examples in the specification provided successful expression of *zmwee1* in E.coli and inhibition of cyclin dependent protein kinase. In Ex parte Vogelstein, the specification provided parts of p53 gene required for p53 function and parts that are not required for p53 function. Unlike in Ex Parte Sun and Ex parte Vogelstein, the instant specification fails to show blast resistance activity by SEQ ID NO: 7 in a transgenic host cell.

### ***Written Description***

Claims 1-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated

for the reasons of record as set forth in the last Office action of 03/11/05. Applicant's arguments filed 07/20/05 have been fully considered but are not deemed persuasive.

Applicant correctly states the requirements of written description as set forth in the Guideline and in MPEP and related case law, *Purdue Pharm L.P. v. Faulding In.*, 230 F.3d 1320 1323, 596 USPQ2d 1481, 1483 (Fed. Cir. 2000); *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1569 (Fed. Cir. 1997). Applicant argues that claims recite both defined structural and functional characteristics, therefore meet the written description requirement (response, p. 15).

This is not persuasive because nucleic acids encoding polypeptides comprising any 40 contiguous amino acids of SEQ ID NO: 8 are not expected to meet the functional characteristics as recited in the claims. Substantial variation in structures and function is expected among nucleic acids encoding polypeptide having any 40 contiguous amino acids of SEQ ID NO: 8 in common. While Applicant discloses LRR-NBS domains to describe that claimed nucleic acids, every 40 contiguous amino acids of SEQ ID NO: 8 does not contain LRR-NBS domains. Therefore, the disclosure of SEQ ID NO: 7, and five other sequences also from rice is insufficient to describe the genus of nucleic acids encoding a polypeptide comprising any 40 contiguous amino acids of SEQ ID NO: 8. Consequently, the specification has not provided an adequate description for DNA constructs, vectors, plant cells and plants comprising said nucleic acid molecules. Therefore, the rejection is proper.

***Claim Rejections - 35 USC § 102***

Claims 1-6 and 8-12, 14-21 are rejected under 35 U.S.C. 102(b) as being



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anticipated by Yano et al (US 6, 274, 789 B1). This rejection is repeated for the reasons of record as set forth in the last Office action of 03/11/05. Applicant's arguments filed 07/20/05 have been fully considered but are not deemed persuasive.

Applicant asserts that the nucleic acid of the claims would not read on the nucleic acid disclosed by Yano et al because the claims as amended recite specific hybridization conditions (response, p. 17, 1<sup>st</sup> full paragraph).

This is found persuasive because the claims recite "a complement" which reads on a nucleic acid of any length that could be a nucleic acid with as few as 5 nucleotides. The specification does not define "a complement", therefore it is open to individual interpretations. Therefore, the nucleic acid disclosed by Yano would hybridize to "a complement" of SEQ ID NO: 7 under the hybridization conditions as set forth in the claims, absent evidence to the contrary. Therefore, Yano et al teach all claim limitations. The rejection, therefore, is proper.

Claims 1-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Hodges et al (US 5, 677, 175 A). This rejection is repeated for the reasons of record as set forth in the last Office action of 03/11/05. Applicant's arguments filed 07/20/05 have been fully considered but are not deemed persuasive.

Applicant asserts that the nucleic acid of the claims would not read on the nucleic acid disclosed by Hodges et al because the claims as amended recite specific hybridization conditions (response, p. 17, 1<sup>st</sup> full paragraph).

This is found persuasive because the claims recite "a complement" which reads on a nucleic acid of any length that could be a nucleic acid with as few as 5 nucleotides.

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The specification does not define "a complement", therefore it is open to individual interpretations. Therefore, the nucleic acid disclosed by Hodges would hybridize to "a complement" of SEQ ID NO: 7 under the hybridization conditions as set forth in the claims, absent evidence to the contrary. Therefore, Hodges et al teach all claim limitations. The rejection, therefore, is proper.

**Remarks**

No claim is allowed.

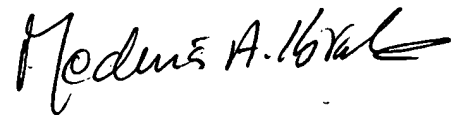
**Contact Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM . Before and after final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Amy Nelson, can be reached at (571) 272-0804.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

9/27/05  
Mai



**MEDINA A. IBRAHIM  
PATENT EXAMINER**